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**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER  
264-011-USP

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/562392

INTERNATIONAL APPLICATION NO.  
PCT/EP2004/050967

INTERNATIONAL FILING DATE  
1 June 2004

PRIORITY DATE CLAIMED  
19 June 2003

**TITLE OF INVENTION**

### Anesthetic Composition for Topical Administration Comprising Lidocaine, Prilocaine and Tetracaine

APPLICANT(S) FOR DO/EO/US

**Fernando Bouffard Fita**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau. (courtesy copy)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☒ A power of attorney and/or change of address letter. (as part of Declaration)
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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| U.S. APPLICATION NO. <b>10/562392</b><br>(known as 37 CFR 1.5)   |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2004/050967                            |         | ATTORNEY'S DOCKET NUMBER<br>264-011-USP  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
|--|--------------|---|---------|--|--------------|--------------|--------------|---|-----------|---------|---------|--------------------|---------|---|---------|---|------|--|---------|--|--|----|------|------|------|
| 20. Other items or information:<br><br>Certificate of Mailing by Express Mail; USPTO Return Postcard   |              |   |         |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| The following fees have been submitted   |              |   |         | <b>CALCULATIONS      PTO USE ONLY</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... <b>\$300</b>   |              |   |         | <b>\$ 300.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))<br><br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... <b>\$0</b><br>All other situations..... <b>\$200</b>  |              |   |         | <b>\$ 200.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))<br>If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... <b>\$0</b><br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... <b>\$100</b><br>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... <b>\$400</b><br>All other situations..... <b>\$500</b>   |              |   |         | <b>\$ 400.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <b>TOTAL OF 21, 22 and 23 =</b>  |              |   |         | <b>900.00</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br>The fee is <b>\$250</b> for each additional 50 sheets of paper or fraction thereof.   |              |   |         | <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:15%;">Total Sheets</th> <th style="width:15%;">Extra Sheets</th> <th style="width:35%;">Number of each additional 50 or fraction thereof (round up to a whole number)</th> <th style="width:15%;">RATE</th> </tr> <tr> <td style="text-align: center;">- 100 =</td> <td style="text-align: center;">/50 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$250</td> </tr> <tr> <td colspan="3"></td> <td style="text-align: center;">\$ 0</td> </tr> </table> |              | Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE      | - 100 = | /50 =   | 0                  | x \$250 |   |         |   | \$ 0 |  |         |  |  |    |      |      |      |
| Total Sheets   | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE    |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| - 100 =  | /50 =        | 0   | x \$250 |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
|  |              |   | \$ 0    |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| Surcharge of <b>\$130.00</b> for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).   |              |   |         | <b>\$ 0</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:15%;">CLAIMS</th> <th style="width:15%;">NUMBER FILED</th> <th style="width:15%;">NUMBER EXTRA</th> <th style="width:15%;">RATE</th> </tr> <tr> <td>Total claims</td> <td style="text-align: center;">20 - 20 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$ 50</td> </tr> <tr> <td>Independent claims</td> <td style="text-align: center;">3 - 3 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$200</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td style="text-align: center;">+ \$360</td> </tr> </table> |              |   |         | CLAIMS   | NUMBER FILED | NUMBER EXTRA | RATE         | Total claims  | 20 - 20 = | 0       | x \$ 50 | Independent claims | 3 - 3 = | 0 | x \$200 | MULTIPLE DEPENDENT CLAIM(S) (if applicable) |      |  | + \$360 | <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">\$</td> </tr> <tr> <td style="text-align: center;">\$ 0</td> </tr> <tr> <td style="text-align: center;">\$ 0</td> </tr> <tr> <td style="text-align: center;">\$ 0</td> </tr> </table> |  | \$ | \$ 0 | \$ 0 | \$ 0 |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA  | RATE    |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| Total claims   | 20 - 20 =    | 0   | x \$ 50 |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| Independent claims   | 3 - 3 =      | 0   | x \$200 |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |   | + \$360 |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| \$   |              |   |         |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| \$ 0   |              |   |         |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| \$ 0   |              |   |         |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| \$ 0   |              |   |         |  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |         | <b>\$ 900.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.  |              |   |         | <b>\$ 450.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <b>SUBTOTAL =</b>  |              |   |         | <b>\$ 450.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).   |              |   |         | <b>\$ 0</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <b>TOTAL NATIONAL FEE =</b>  |              |   |         | <b>\$ 450.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property  |              |   |         | <b>\$</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
| <b>TOTAL FEES ENCLOSED =</b>   |              |   |         | <b>\$</b>  |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
|  |              |   |         | Amount to be refunded:   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
|  |              |   |         | Amount to be charged   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |
|  |              |   |         | <b>\$ 450.00</b>   |              |              |              |   |           |         |         |                    |         |   |         |   |      |  |         |  |  |    |      |      |      |

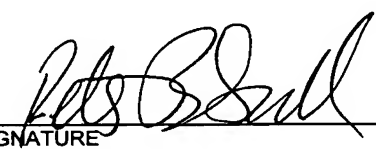
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- 10/562392
- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 50-3199 in the amount of \$ 450.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3199. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 45346  
Hensley Kim & Edgington, LLC  
1660 Lincoln Street  
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Denver, Colorado 80264  
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SIGNATURE

Peter B. Scull

NAME

37,932

REGISTRATION NUMBER

Date: December 19, 2005

10/562392  
IAP5 Rec'd PCT/PTO 19 DEC 2005

Attorney Docket No. 264-011-USP  
Express Mail Label No. EV 703 995 067 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

|            |  |                   |
|------------|--|-------------------|
| Applicant  | : Fernando Bouffard Fita   | Confirmation No.: |
| Appln. No. | : Not yet assigned   | Group Art Unit:   |
| Filed      | : herewith   | Examiner:         |
| Title      | : Anesthetic Composition for<br>Topical Administration Comprising<br>Lidocaine, Prilocaine and<br>Tetracaine |                   |

CERTIFICATE OF MAILING BY EXPRESS MAIL


Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The undersigned hereby certifies that the following documents:

1. Certificate of Mailing by Express Mail (1 page);
2. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission Under 35 U.S.C. 371 (3 pages); and
3. Courtesy copy of International Application No. PCT/EP2004/050967 (15 pages);
4. Preliminary Amendment (7 pages);
5. Combined Declaration and Power of Attorney for Patent Application (executed) (3 pages);
6. Information Disclosure Statement Form PTO/SB/08a (1 page) with copies of foreign and U.S. publication references attached; and
7. USPTO Return Postcard

relating to the above application, were deposited as "Express Mail" under 37 CFR § 1.10, Mailing Label No. EV 703 995 067 US, with the United States Postal Service addressed to Mail Stop PCT Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19<sup>th</sup> day of December 2005.

  
\_\_\_\_\_  
Mailer's Signature  
Print Name: Pamela L. Rader

Hensley Kim & Edgington, LLC  
USPTO Customer No. 45346  
Tel: 720-377-0770  
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